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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,691	06/03/2002	Stephen Gill	PA-9947	3741
36335	7590	10/26/2004	EXAMINER	
AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/069,691

**Applicant(s)**

GILL ET AL.

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Response to Amendment***

The amendment filed 8/16/2004 has been entered.

***Response to Arguments***

Applicant's arguments filed 8/16/2004 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (US 5,961,952) in view of any one of JP 11099192 or Schott Glaswerke (DE 29609958) or Walther (US 6,200,658), for the reasons set forth in the office action mailed 5/28/2004.

Applicant's arguments filed 8/16/2004 have been fully considered but they are not persuasive.

Applicant asserts that the person skilled in the art would focus on the repeated teachings in Crane that solubility agents and reducing agents are important and would be motivated on improving these elements.

This is not found persuasive because there is nothing to suggest that one skilled in the art would limit themselves to the specific benefits taught Crane. One skilled in the art would be motivated to consider the art as a whole, looking at any possible benefits which may be in the same field of endeavor or reasonable pertinent to the problem being solved. Clearly, Crane teaches the use of metal complexes as radiopharmaceuticals which are kit form. This is well known in the art. The secondary references teach that pharmaceuticals, including radiopharmaceuticals, benefit from being in silicon coated vials. One skilled in the art would not only look at Crane for improvements in the field of radiopharmaceuticals, but would look to any relevant art. This would include the cited secondary references that teach various advantages of using silicon coated vials as containers for pharmaceuticals and/or radiopharmaceuticals.

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In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Crane teaches radiopharmaceuticals that are in containers in kit form. The secondary references teach that vials that are coated with silicon are advantageous as containers for pharmaceuticals and/or radiopharmaceuticals. Thus, the references are in the same field of endeavor (radiopharmaceuticals) and/or reasonably pertinent to the problem being solved, forming kits of radiopharmaceuticals. Clearly, the use of silicon coated vials is a known advantage in the field of pharmaceuticals and radiopharmaceuticals, and therefore one skilled in the art would have been motivated to obtain these benefits for various pharmaceuticals and/or radiopharmaceuticals, such as, those disclosed by Crane. Therefore, the motivation to combine arises from the benefits of the prior art.

Applicant asserts that there is no teaching in Crane of leaching problems and this is the benefit set forth in DE '958.

The primary reference does not need to state a specific problem in the reference for an improvement in the art to be obvious. The leaching problem is taught in the art, by DE '958, that various pharmaceuticals and diagnostic agents suffer from leaching and that problem can be prevented by using silicon coated vials. Clearly, one skilled in the art would see that the benefit would hold true for various pharmaceuticals and diagnostic agents, as taught by DE '958, such as, the pharmaceutical/diagnostic agent disclosed by Crane.

Applicant asserts that Walther is silent on vials, but only recites ampoules and bottles.

This is not persuasive as there is no clear delineation between a vial and a bottle or ampoule. These terms seem interchangeable and clearly, given its broadest reasonable interpretation, a vial, as claimed, would encompass a bottle or ampoule, especially since they are for the same use as a container for a pharmaceutical.

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Applicant also asserts that Walther does not limit the coating to silicon, but teaches a few possibilities and there is nothing to point to silicon.

This is not found persuasive because Walther only teaches three possibilities (or mixtures thereof), and one skilled in the art would clearly envisage the use of SiO<sub>2</sub> from this very limited number of possibilities shown in the abstract, as well as, the claims.

Applicant asserts that Crane teaches that solubilization aids are a preferred embodiment to overcome absorption problems and thus would not be motivated to look to solve this same problem by the disclosure of this benefit as taught by JP '192.

This is not found persuasive. Rather this is motivation to combine, as both Crane and JP '192 realized the same problem which needed to be solved, i.e., absorption problems. Just because Crane realizes this problem and finds a means to address this problem in no way means that this would be the end of this issue. Clearly, one skilled in the art would be motivated to consider all the means available to circumvent a problem known in the art. Since Crane and JP '192 both address the same problem, and are in the same field of endeavor, one skilled in the art would have been motivated to combine these two references. The art as a whole clearly teaches advantages of using silicon coating vials for vials in the same field of endeavor as Crane, as well as, particularly pertinent to the problem being solved, as Crane teaches that absorption is a problem and the cited prior art teaches that absorption of radiopharmaceuticals may be solved using silicon coated vials.

### ***Conclusion***

No claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action

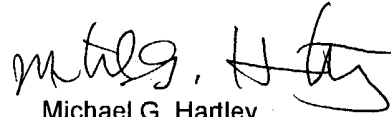
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is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

10/25/2004